The Pending Claims

Claims 1, 5-15, 19-27 and 31-38 are currently pending. Claims 1 and 5-14 are directed to polymeric compositions. Claims 15 and 19-26 are directed to pharmaceutical compositions. Claims 27 and 31-38 are directed to the method of treating biological disorders in a mammal.

The Advisory Action

The Advisory Action indicates that the rejection of claims 1, 5-15, 19-27 and 31-38 as non-enabling under 35 U.S.C. §112 because of undue experimentation is being maintained. Reconsideration of this rejection is hereby requested.

A patent specification meets the enablement requirement of 35 U.S.C. §112 even though some experimentation may be necessary to practice the claimed invention so long as the amount of experimentation is not unduly extensive. Thus, a considerable amount of experimentation is permissible, if it is merely routine, or if the specification provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed to enable the determination of how to practice a desired embodiment of the invention. *Ex parte Jackson*, 217 U.S.P.Q. 804, 807 (CCPA 1982), *cited with approval in PPG Industries, Inc. v. Guardian Industries Corp.*, 75 F.3d 1558, 37 U.S.P.Q. 2d 1618 (Fed. Cir. 1996).

The subject application satisfies both requirements. The experimentation the Examiner refers to is merely routine in view of Applicants' teachings. The specification shows that the reaction allowing the $N_2O_2^-$ functional group to attach to the biopolymer occurs at the C-terminus and at the N-group of biopolymers, particularly as demonstrated in the Examples. The fact that the biopolymeric backbones in the various species of biopolymers may be different is irrelevant to the enablement inquiry. Being biopolymers, they all would have reactive sites available for bonding of the X-NONO or NONO-X structures as disclosed in the specification. Moreover, the side reaction propositions, solubilities and temperature sensitivity variations (assuming they exist as contended by the

Office) simply fall into the category of routine experimentation that could be carried out by the skilled artisan given Applicants' disclosure.
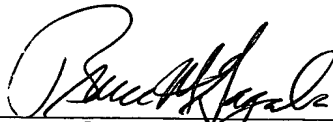
In addition, Applicants have provided the necessary guidance to direct the skilled artisan how to proceed to make different embodiments within the scope of the claims. The specification, at pages 16 and 17, for example, teaches bonding, as is shown in the Examples, of the NONO functional group to an atom in the biopolymer backbone, a group pendant to the biopolymer backbone or by entrapment in the biopolymer matrix. The routine nature of any experimentation that may be necessary and the guidance provided by the specification to achieve different types of biopolymeric NONOates within the scope of the claims lead to only one conclusion: the specification is enabling. Therefore, claims 1, 5-15, 19-27 and 31-38 are allowable.

Conclusion

The application is considered to be in good and proper form for allowance, and the Examiner is respectfully requested to pass this application to issue.

If, in the opinion of the Examiner, a telephone conference would expedite the prosecution of the subject application, the Examiner is invited to call the undersigned attorney.

Respectfully submitted,

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Date: October 30, 1998

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CERTIFICATE OF FACSIMILE

I hereby certify that this RESPONSE TO ADVISORY ACTION (along with any documents referred to as being attached or enclosed) is being transmitted by facsimile on the date shown below to Examiner P. Kulkosky, Assistant Commissioner for Patents, Washington, D.C. 20231, fax no. (703) 308-4556.

Date: _October 30, 1998_   _Becky Williams_

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